

## REMARKS

### **I. Status of the Claims**

Claims 18, 19, 24-26, and 33-60 are pending in the application. Claims 33-60 stand withdrawn pursuant to a restriction requirement, and claims 59 and 60 are canceled without prejudice or disclaimer. Claims 24-26 are rejected as indefinite under 35 U.S.C. §112, second paragraph, as lacking written description and enablement under 35 U.S.C. §112, first paragraph, and as anticipated under 35 U.S.C. §102. No grounds for rejection are offered against claims 18 or 19, despite their being indicated as rejected.<sup>1</sup> The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

### **II. Objections**

#### **A. Specification**

The Abstract is again objected to for described non-elected embodiments. Applicants request that the objection to the Abstract be held in abeyance as applicants may be entitled to rejoinder of one or more method claims.

#### **B. Claims**

Claims 18 and 19 are objected to as the term “non-Vac14 sequences” is said to “lack antecedent basis in the specification.” Applicants to not understand the objection. Does the examiner argue that this term is not adequately defined or supported in the specification? If so, applicants traverse on the grounds that the term has plain and clear meaning – non-Vac14 sequences are those sequences *other* than Vac14 sequences. Moreover, the objection of claim 18

is improper as it does not use the term “non-Vac14 sequences.” Reconsideration and withdrawal of the objection is requested.

Claim 25 is objected to for the use of “is” rather than “has.” Applicants traverse as (a) the claim is clear as written, and (b) the examiner’s suggested change would render the claim grammatically incorrect. Reconsideration and withdrawal of the objection is requested.

Claims 25 and 26 remain objected to as substantial duplicates of each other. Applicants again traverse. As offered before, the plain language of the claims reveals that claim 25 is directed to particular *overall lengths* of the oligopeptide, whereas claim 26 refers to the number of *consecutive residues* from the referenced sequence. These are distinct embodiments and do not run afoul of the “claim duplication” prohibition of 37 C.F.R. §1.75. Whether the examiner has misunderstood or ignored the preceding, applicants can offer nothing further. Reconsideration and withdrawal of the objection is again requested.

### **III. Rejections Under 35 U.S.C. §112**

#### **A. First Paragraph**

Claims 24-26 stand rejected as lacking an adequate written description or enabling disclosure. Applicants traverse both rejections as lacking adequate legal and factual foundations.

**Written Description.** The examiner now examines only 3 factors for analyzing the written description requirement, and thus it is presumed that the examiner concedes on two of the factors previously examiner. Of the remaining ones, level of skill in the art clearly mitigates *in favor* of written description as the skill is *admittedly* high, and thus before the analysis truly

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<sup>1</sup> Applicants request that the next action properly indicate the status of these claims.

begins, applicants have 3 of 5 factors weighing their favor. The examiner conveniently dismisses this fact when coming to a conclusion regarding description, however.

With regard to physical and/or chemical properties, applicants submit that one use of the claims oligopeptides is to produce antibodies, which in turn can be used to assay for the full-length protein. Though not a universal property of each and every polypeptides, *in the absence of any evidence to the contrary, applicants submit that one of skill in the art would presume that many if not most peptides would be useful in this context.* The examiner acknowledges this but then attempts to rebut this line of argument by citing to Prescott *et al.* This citation is highly misleading and completely irrelevant to applicants' argument *as the Prescott reference is discussing immunotherapy, not the simple production of antibodies.* To even attempt to support the rejection in this way belies a fundamental misunderstanding of the invention, or even worse, a complete lack of foundational support in the literature for this rejection. Moreover, the examiner's continued digressions into "inhibitory activity" remain unnecessary in determining written description.

With regard to functional characteristics/partial structure, applicants submit that while the number of possible oligopeptides falling within the scope of the claim is large, it is a straightforward matter to identify each of these. Indeed, applicants could easily have generated a sequence listing with each and every peptide using a simple computer program and filled the Patent Office with hundreds of pages of a sequence listing. However, since it would immediately be evident to any skilled artisan upon a reading of the specification what peptides were envisioned, there would be no reason so submit such a listing. And again, one can easily determine which oligopeptides can generate antibodies, and in the absence of some *meaningful*

reason to doubt that property, one would also assume that a given peptide *would* have such activity.

In sum, while properly citing factors that should be applied to a written description analysis, the examiner then fails to actually *follow* the results of the analysis, and instead focuses on isolated factors that are incorrectly assessed or fail to address the nature of the claimed invention. Reconsideration and withdrawal of the rejection is again therefore respectfully requested.

**Enablement.** Here, again the examiner has made proper reference to the factors under consideration when analyzing enablement under §112, first paragraph. But just as before, the examiner has failed to use valid facts and has come to the incorrect conclusion regarding enablement.

Again, applicants readily admit that the genus of claimed oligopeptides is large. However, it simply cannot be said that the skilled artisan cannot correlate function of the *genus* of oligopeptides of SEQ ID NO:3 with the biological activity of raising antibodies. Again, as noted in the application at page 26, one can use peptides to produce antibodies which can then be used diagnostic applications. And again, while it is true that not *every* oligopeptide will produce antibodies that cross-react with the native Vac14 sequence, one would expect many (in fact the majority) of such oligopeptides to elicit at least a polyclonal response the would react to some extent with a denatured form of SEQ ID NO:3. The examiner's reference to Prsecott *et al.*, as discussed above, is *completely* off the mark as the reference deals with allergy vaccines, not the simple production of antibodies. This is sufficient to enable the peptides generally, and the possible inclusion of a few inoperative species within the scope of a claim does not necessarily render a claim nonenabled. See MPEP §2164.08. "The standard is whether a skilled person

could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art.” Citing *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984). Even a large number of operable embodiments does not always render a claim broader than the enabled scope when undue experimentation is not involved in determining which embodiments are operable. See *In re Angstadt*, 537 F.2d 498, 502-503, 190 USPQ 214, 218 (CCPA 1976). And just as with the written description analysis, the attack on “inhibitory activity” of the peptides is completely irrelevant.

Here, there remains no meaningful challenge to applicants’ argument that raising antibodies or antiserum against a given peptide is trivial from a scientific standpoint, as is the testing of such compositions for reactivity with Vac14. As such, there can be no real question as to the enablement of claims 24-26. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

#### **B. Second Paragraph**

Claims 24-26 stand newly rejected under the second paragraph of §112 for use of the term “about” in claim 24. Applicants traverse, but in the interest of advancing the prosecution, an amendment is provided that overcomes the rejection. Reconsideration and withdrawal of the rejections is therefore respectfully requested.

#### **IV. Rejections Under 35 U.S.C. §102**

Claims 24-26 stand rejected as anticipated by Robert *et al.*, which is said to disclose an oligopeptide of 10 residues with 100% identity to a portion of SEQ ID NO:3. Applicants have

amended the claims to recite a minimum identity (and a minimum length) of 15 residues. Thus, the rejections are believed to be overcome, and their withdrawal is respectfully requested.

**V. Conclusion**

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at 512-536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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